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(54) **Ultrasonic recanalization system.**

(57) An ultrasonic recanalization system comprising: an ultrasonic transducer handle (11) comprising a transducer energized by a switch (12), and said transducer is connected to an ultrasonic console (20) containing control means of the ultrasonic energy level applied, determined by a measuring device of the frequency and amplitude (13) provided at the tip ending of said transducer; and said ultrasonic transducer transfers the ultrasonic energy through a hollowed tube (14) entered into the patient's arteries through a triple lumen catheter (22) and said ultrasonic tube having at its ending a bent portion (35) with a flexible tip (34) and said triple lumen catheter having a flow blocking device (31) on the outer circumference of its catheter which can be blown up when required to secure the tip position and block the flow of blood near the stenosis blockage site in the artery; and having a concentric canal passage (32) around said ultrasonic hollowed tube, through which a liquid solution can be pumped in from a reservoir by a pump provided in said ultrasonic console; and said solution can then flow out after washing off the stenosis splinters and blood into a second reservoir provided in said console, through said hollowed tube.

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ULTRASONIC RECANALIZATION SYSTEM

This invention relates to an ultrasonic recanalization system for ablation of atherosclerotic stenosis and plaques in human or animal atherosclerotic arteries, to be used in human or animal percutaneous and transcutaneous recanalization (angioplasty).

Background of the invention

Several angioplasty techniques are known in the prior art. The most advanced techniques to date are either those using balloon catheters, or those using laser angioplasty with specific laser systems; or those using high speed rotating cutting blade technique.

The most advanced technologies in this art are described in the following documents:

EP 268,068 filed on 23 October 1986 describes an angioplasty balloon catheter.

Edwards Lis division of Baxter has a commercial balloon catheter marked as Hydracross^{R}.

Trimedyne Inc has a laser angioplasty product marketed as Laserprobe^{R}.

US 4819634 describes the use of the rotary blade catheter technique for atherectomy.

lately scientists decided to apply ultrasonic techniques to recanalization (angioplasty).

Ultrasonic technology has been used widely in dentistry and there are many sophisticated techniques for applying ultrasonic transducers to different probes having to penetrate tissues in between teeth or gums. The modern equipment is supplied with efficient cooling systems, and controls of both temperature frequency and amplitude of the ultrasonic energy emitted at the probe tips.

In surgery, ultrasonic technology has been used for many years; equipment such as Storz ultrasonic nephroscopic sheath (produced by Storz Endoscopy - America Inc.) has been used for a long while in urology service for percutaneous nephrolithotomy, to disintegrate calcium blocks. Saline at 4° C is used for cooling the overheated probe.

The complete procedure is discussed in an article published by M.G. Eugaras and al in "The journal of Thoractic and Cardiovascular Surgery 1988" 95 : 1038 - 40 demonstrating the advantage of the ultrasonic system.

Using double or triple lumen catheters to enter arteries and perform recanalization procedures by either of the known arts (balloon, laser) or by rotational thrombectony, using a high speed rotating cutting blade inserted through a catheter into the artery, the blade minces the stenosis obstruction, thus enlarges the artery lumen. The further technique of using the balloon can then be applied. It was therefore an obvious development in the art to try and apply the sophisticated ultrasonic technology, using a double or triple lumen catheter with the modified ultrasonic probes to perform recanalization in arteries.

The use of ultrasonic angioplasty system is described in detail by R. Seigal and al who published a detailed report "Ultrasonic plaque ablation, for recanalization or occluded arteries".

The report was published in Circulation p.1443 in December, 1988.

G. Dobrinski and al published their work on "Ultrasonic Angioplasty" in the journal "Archive des Maladies du Coeur 1989; 82; 377 - 80.

EP 316,796 published on 24 May, 1989 describes an ultrasonic device having an ultrasonic generator connected to a probe extending from the end of a catheter. The bulbous tip of the probe is placed against the blockage. A radiographic contrast fluid can be introduced into the catheter to make the blood vessel clearly visible on an X-ray monitor.

US 4,808,153 published 28 February, 1989, describes a device for removing plaque from arteries. The vibrations are transferred through a hollow member of an inert rigid material such a Titanium. Several vibrating members are disposed around the hollow member, all activated by the ultrasonic frequency. A flexible catheter is disposed on the hollowed member, having a forward end covering the hollow member ending and having a blunt disposition.

WO 8,906,515 published on 27 July 1989 describes an ultrasonic angioplasty device employing a frequency generator, a piezeolectroc transducer, and a horn. An ultrasonic transmission member is employed to introduce the device into the patient's circulatory systems. Said member is formed as a wire of aluminum or similar alloy in an annealed state.

In all these prior art works, it was clearly demonstrated that the ultrasonic technique for angioplasty is viable if carried out carefully without risking any damage to the inner surface of the arteries during the application and specifically when approaching the stenosis blocked sites; and appropriate cooling is provided.

It is therefore the purpose of this invention to provide an ultrasonic recanalization system having sufficient controls and specific applicators which will minimize the risk of damage to the arteries before, during, and after the ultrasonic ablation of the athrerosclerotic plaques. As well as assure that the stenosis splinters released during the applica-

tion will not block the ultrasonic hollowed tip. The ultrasonic tip provided will have appropriate cooling means on the inner and outer lumen.

The ultrasonic recanalization technique provided will enable ablation of prepherial and coronary athriosclerotic arteries in humans and animals. It may also be used in urology service for percutaneous nephrolithomy decalcification, as well as decalcification of blockages in the pancreas, etc.

Brief description of the invention

The ultrasonic recanalization system herein provided comprises: an ultrasonic transducer member comprised in a handle applied by a switch; and said transducer is connected to an ultrasonic console containing control means of the ultrasonic energy level applied, determined by a measuring device of the frequency and amplitude provided at the tip ending of said transducer; and said ultrasonic transducer transfers the ultrasonic energy through a hollowed tube entered into the patient's arteries through a triple lumen catheter, and said ultrasonic tube having at its ending a bent portion with a flexible tip; and said triple lumen catheter having a flow blocking device such as a balloon on the outer circumference of its tip which can be blown up when required to secure the catheter position and block the flow of blood near the stenosis blockage site in the artery; and having a concentric canal passage around said ultrasonic hollowed tube, through which a liquid solution can be pumped in from a reservoir by a pump provided in said ultrasonic console; and said solution can then flow out after washing off the stenosis splinters and blood into a second reservoir provided in said console, through said hollowed tube.

In the preferred embodiment said ultrasonic hollowed tip ending is provided with a spring having high flexibility to enable the user to have maximal adaptation to variations of movement of the ultrasonic tube inside the arteries, specifically when reaching contact with rigid stenosis or plaque blockages, or when reaching contact with soft flexible artery inner surface. Said tip ending prevents perforation of the artery.

In the preferred embodiment said hollowed tube tip ending is provided with an ending in form of a three cheak rotor preventing blockage of said hollowed tube by stenosis sucked out through the hollowed tube.

In the preferred embodiment the ultrasonic hollowed tube and tip are made of a rigid material longitudinally, and flexible in all other directions with an inner and outer special protection coating such as Teflon^{R} or a similar inert tough and smooth material.

In the preferred embodiment said ultrasonic console comprises frequency, gain and flow control knobs to be manually set by the user at the required levels.

In the preferred embodiment the ultrasonic console contains a computerized automatic control system set by a computer program, controlling the ultrasonic energy level transmitted by said ultrasonic transducer; and the flow rate of said solution pumped into the arteries by said positive displacement pump through said triple lumen catheter.

In the preferred embodiment the reservoir containing said solution to be pumped in, is installed as part of said console, having also a temperature control assuring the appropriate required temperature of the solution. Such temperature to be preferably 37 $^{\circ}$ C.

In the preferred embodiment said solution is a saline with a specific appropriate cleaning chemical and an agent avoiding excess oxygen build up. Said solution could also contain strained blood suitable to be pumped into the artery to wash out the stenosis splinters after ultrasonic energy was applied. In the preferred embodiment the inwards flow of the solution through the outer lumen of the triple lumen catheter, and the outwards flow of the washout splinters of the stenosis with the blood and solution is through the inner lumen of the hollowed tube. Thus the counter flow system acts as a cooling media to the ultrasonic system.

In the preferred embodiment a second thermocouple is provided at the distal end of the ultrasonic hollowed tip, which will alert the system in case of excess temperature build up in the proximal tip end endangering the artery tissue.

In the preferred embodiment said ultrasonic handle includes the ultrasonic transducer which is energized by a switch mounted on said handle; and said strain gauge measuring the frequency and amplitude of the ultrasonic tip is mounted on the exit of said tip from the handle.

In the preferred embodiment said balloon at the tip ending of said triple lumen catheter is inflated by a syringe connected by an air connecting tube to an entry adaptor of said triple lumen catheter.

In the preferred embodiment said syringe is connected to said air tube through a control valve.

The invention can be best understood in reference to the attached drawings:

Fig. 1 illustrates a three dimensional view of the complete system.

Fig. 2 Illustrates a longitudinal cross section of the artery at the stenosis site, showing the ultrasonic hollowed tip.

Fig. 3 and Fig. 4 illustrate two cross sections of the artery and triple lumen catheter at different positions.

Fig. 5 illustrates a control flow chart of the

system.

Detailed description of the invention

Fig. 1 illustrates an ultrasonic transducer handle 11, comprising a transducer (not seen) energized by the switch 12 mounted on the handle 11, having at its tip a strain gauge 13 to measure the frequency and amplitude of the ultrasonic energy emitted through the hollowed tip 14 at the proximal tip ending in the artery. The gauge 13 transmits data to the ultrasonic control circuit 26 included in the console 20. The ultrasonic transducer (not seen) receives its power from an ultrasonic generator (not seen) placed in the console 20 through the cable 15. Three control knobs 8, 9, 10 are provided for manual control of frequency, power and liquid flow rate. Suction is applied through the hollowed tip 14 by a positive displacement pump 17 through a suction pipe 16 connecting the hollowed tip 14 to the console 20 to the wash out liquid reservoir 18.

The hollowed tip 14 is placed into a guiding tube 21 leading the hollowed tube into a triple lumen catheter 22 through the adaptor 25. The adaptor 25 is also connected to the air connecting pipe 24, and to the solution supply tube 23 which connects to the solution reservoir 19 in the console 20. The solution is pumped into the catheter by the pump 17. The solution temperature is controlled by a temperature controller 26 assuring a required temperature (usually about 37° C).

The air is inflated into the triple lumen catheter 22 by a syringe 28 through an air control valve 27. A temperature controller 29 is provided at the distal end of the hollowed tip 14 controlling the temperature build up near the artery of the hollowed tip ending 34 (seen in Fig. 1(a)).

Fig. 1 (a) illustrates an enlarged section of the artery 30 showing the ending of the triple lumen catheter 22, having a balloon 31 on its outer circumference inflated by the syringe 28 as explained above. The ultrasonic hollowed tip 14 goes through the catheter 22 and has a circumferential canal 32 through which the solution is pumped in from the solution reservoir 19. The stenosis - plaque blocking the artery 30 is shown by 33. The hollowed tip ending is shown by 34

Fig 2 illustrates a more explicit cross section of the artery 30 at the stenosis cleaning site.

The stenosis 33 blocks the artery 30. The catheter 22 has an outer balloon ring 31 securing its position and blocking the blood flow when the balloon 31 is inflated. The circumferential canal 32 allows inflow of the solution pumped in. The hollowed dip 14 passes through the central passage of the catheter 22. The hollowed tip 14 has an ending 34 in form of a flexible spring, and the tip ending has a bent portion 35 with an ending 36 specifically designed to prevent flow blockage. The suction is applied through the hollowed tip 14 to suck out the blood solution and stenosis fragments after applying ultrasonic energy to tip 14.

Fig. 3 illustrates a view of the hollowed tip ending of the hollowed tube 14. The three cheak rotor type ending 36, and the spring attachment 34.

Fig. 4 illustrates the cross section of the artery 30 showing the catheter 22 having a circumferential passage canal 32, and the air channel 35 for inflation and deflation of the balloon 31, and the hollowed tip tube 14 passing concentrically. 37 are the guiding ribs of catheter to secure the concentric position of the hollowed tube 14.

Fig. 5 illustrates the control flow chart. The pump 17 having two heads enabling by the first head to pump in the solution from reservoir 19 through the outer lumen canal of the catheter 22; and by the second head to pump out the washout liquids by suction containing the stenosis splinters, through the hollowed tube 14, into the reservoir 18.

The temperature of the solution in reservoir 19 is controlled by a themocople 26 which activates the heating element 43. A constant temperature of 37° C is kept under regular conditions.

The ultrasonic transducer 41, placed inside the handle 11 (not seen), receives its power from an ultrasonic generator 42 placed inside the console 20 (not seen), through the cable 15 (not seen). The strain gauge 13 controls the frequency and amplitude of the ultrasonic energy at the tip of the hollowed tube 14, and thermocouple 29 controls the temperature of the outflowing wash liquid at the exit of the hollowed tube 14. When the temperature exceeds a set level an alert is triggered off. The control circuit 44 situated inside the console 20 (not seen). Control lines connect the control circuit 44 with the pump 17, the heating element 43 and thermocouples 26, and 29, and with the ultrasonic generator 42 and the strain gauge 13.

While the invention has been described in reference to the attached drawings, it should be appreciated that other ultrasonic recanalization systems can be built using the key features of this invention. they should all be regarded as being part of this invention.

Claims

1. An ultrasonic recanalization system comprising: an ultrasonic transducer handle comprising a transducer energized by a switch; and said transducer is connected to an ultrasonic console containing control means of the ultrasonic energy level applied, determined by a measuring device of the frequency and amplitude provided at the tip ending of said transducer;

and said ultrasonic transducer transfers the ultrasonic energy through a hollowed tube entered into the patient's arteries through a triple lumen catheter, and said ultrasonic tube having at its ending a bent portion with a flexible tip; and said triple lumen catheter having a flow blocking device on the outer circumference of its catheter which can be blown up when required to secure the tip position and block the flow of blood near the stenosis blockage site in the artery; and having a concentric canal passage around said ultrasonic hollowed tube, through which a liquid solution can be pumped in from a reservoir by a pump provided in said ultrasonic console; and said solution can then flow out after washing off the stenosis splinters and blood into a second reservoir provided in said console, through said hollowed tube.

2. An ultrasonic recanalization system as in claim 1 wherein said ultrasonic hollowed tip ending is provided with a spring having high flexibility to enable maximal adaptability to movement variation of said tip in the arteries, giving different reactions when in contact with rigid stenosis or plaque blockage, or with soft artery tissue.

3. An ultrasonic recanalization system as in claim 1 wherein said hollowed tube tip ending is provided with a three cheak rotor, preventing blockage or said hollowed tube tip by stenosis fragments.

4. An ultrasonic recanalization system as in claim 1 wherein said flow blocking device on said triple lumen catheter is a balloon.

5. An ultrasonic recanalization system as in claim 1 wherein said console comprises three knob controls to control manually the frequency, gain and flow levels of the ultrasonic transducer, and the solution liquid supply.

6. An ultrasonic recanalization system as in claim 1 wherein a computerized control circuit is provided in said console, having a computer programme for controlling the ultrasonic energy level transmitted by said ultrasonic transducer; and the flow rate of said solution pumped in through said triple lumen catheter in reference to the temperature of the washout liquid sucked out through said hollowed tube.

7. An ultrasonic recanalization system as in claim 1 wherein said reservoir containing said solution is included in the console; and a temperature control is provided to secure the desired solution temperature.

8. An ultrasonic recanalization system as in claim 1 wherein said solution is saline containing appropriate chemicals for cleaning the artery treated by the ultrasonic tip, as well as applying an agent to avoid over reaction to sudden increase in oxygen content.

9. An ultrasonic recanalization system as in claim 7 wherein said solution also contains strained blood.

10. An ultrasonic recanalization system as in claim 1 wherein the inwards flow of said solution is through the outer lumen of said triple lumen catheter, and the outwards flow of said washout liquid containing the stenosis splinters with blood is through the inner lumen of said hollowed tube, thus providing a cooling system to said ultrasonic tip emitting ultrasonic energy in the artery.

11. An ultrasonic recanalization system as in claim 1 wherein said ultrasonic transducer is included in a handle and energized by a switch mounted on said handle, or on a pedal.

12. An ultrasonic recanalization system as in claim 1 wherein a strain gauge measuring the frequency and amplitude at said hollowed tube tip is mounted at the distal end of said hollowed tube.

13. An ultrasonic recanalization system as in claim 1 wherein said balloon at the proximal ending of said triple lumen catheter is inflated by a syringe connected through an air connecting tube to said adaptor of siad triple lumen catheter.

14. An ultrasonic recanalization system as in claim 1 wherein said ultrasonic hollowed tube and tip are made of a rigid longituidinal material, flexible in all other directions with an inner and outer protection coating such as Teflon^{R} or a similar inert tough and smooth material.

15. An ultrasonic recanalization system as in claim 1 wherein a thermocouple is provided at the distal ending of said hollowed tube, which causes alert when an excess temperature is recorded, indicating potential danger at the ultrasonic tip in the proximal position near the artery.

FIG. 1

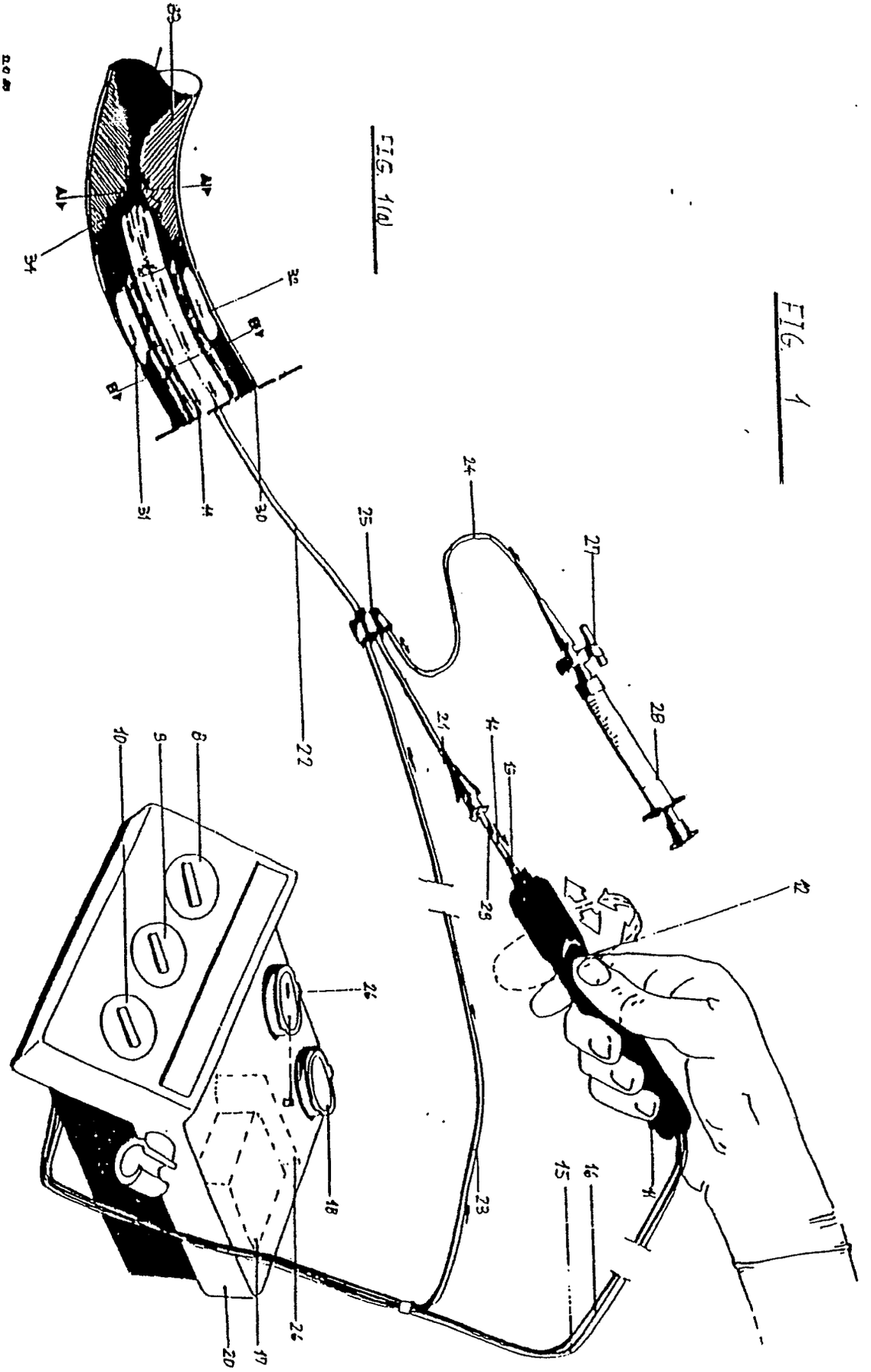
FIG. 1(a)
3
A1
A1
34
32
B1
B1
31
4
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22
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28
21
4
13
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42
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9
8
26
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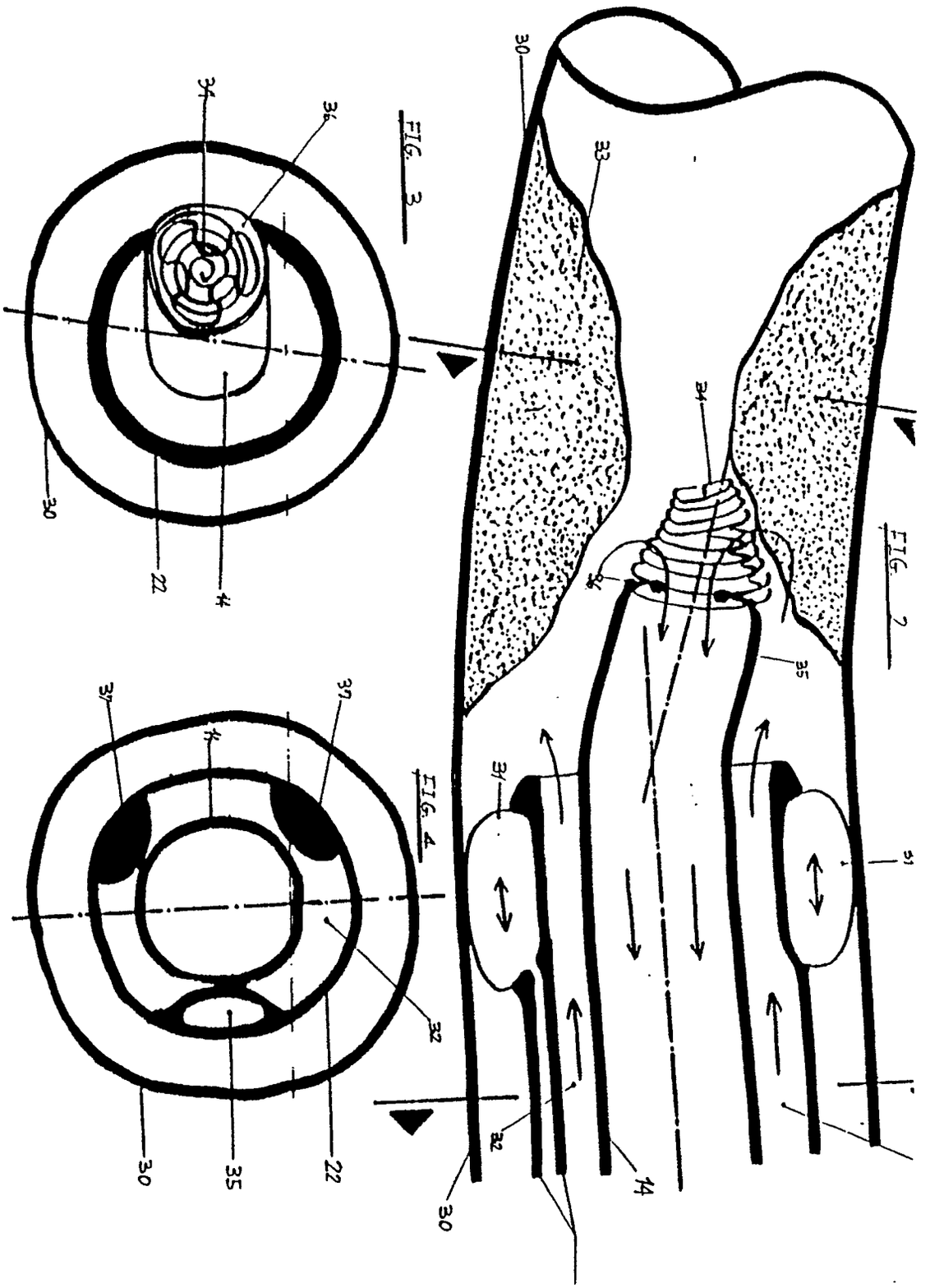
30
33
34
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14
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36
37
FIG. 2
FIG. 3
FIG. 4

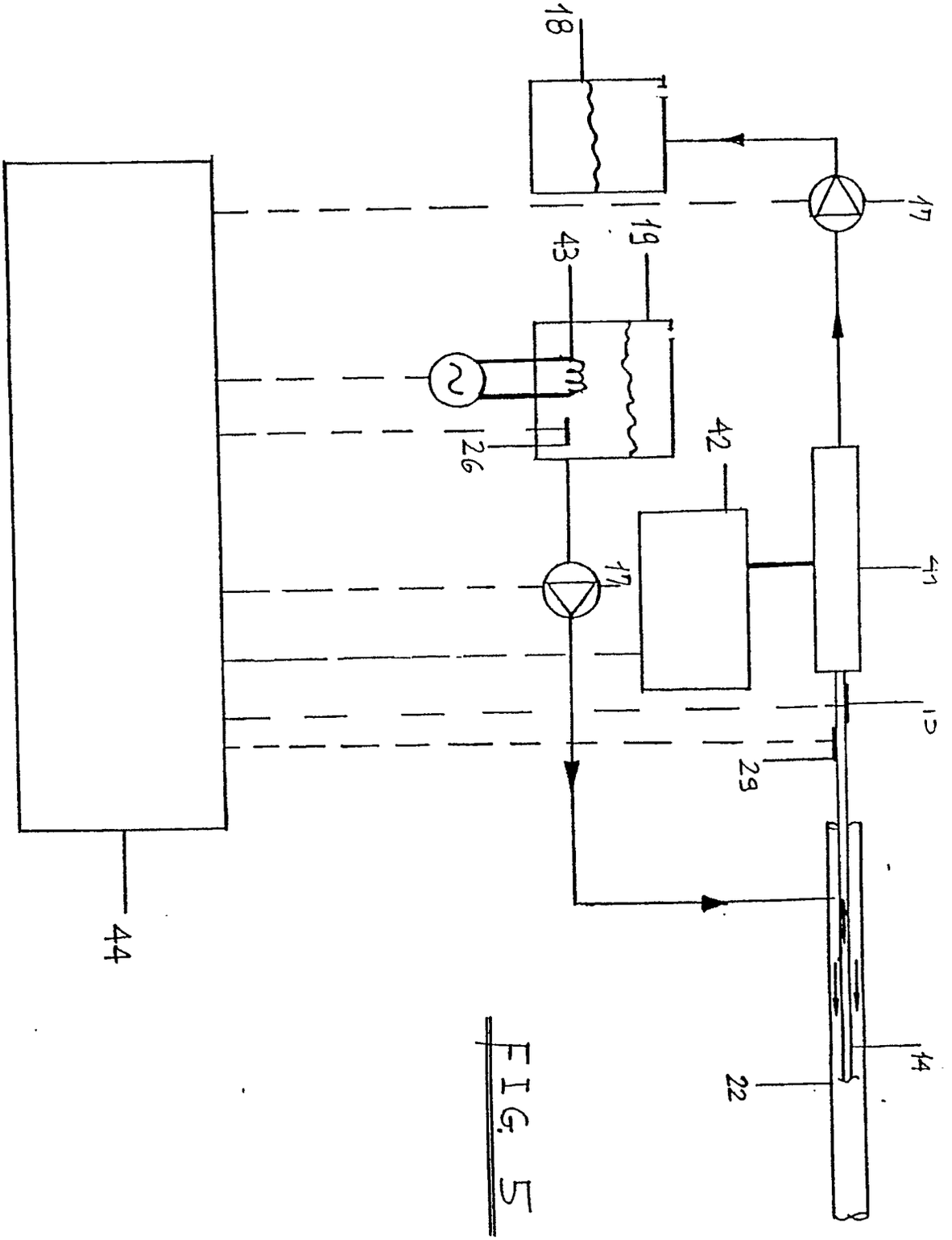

FIG. 5

European Patent Office

EUROPEAN SEARCH REPORT

Application Number

EP 90 31 3671

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int. Cl.5)
A	EP-A-0 316 796 (DONMICHAEL) * Column 8, line 39 - column 9, line 47; figure 3 *	1,4	A 61 B 17/22
A	US-A-4 063 557 (WUCHINICH et al.) * column 7, lines 9-59; column 8, line 2 - column 9, line 29; figures 14 *	1	
A	DE-U-8 816 114 (NAUCNO-ISSLEDOVATEL'SKY) * Page 5, lines 20-31; figure 1 *	1	
A	DE-A-3 720 424 (NAKADA) * Column 8, line 41 - column 9, line 8; figure 10 *	1,2	
A	US-A-4 030 503 (CLARK) * Column 1, lines 38-55; figure 1 *	1,2	

TECHNICAL FIELDS SEARCHED (Int. Cl.5)

A 61 B
A 61 F

The present search report has been drawn up for all claims

Place of search	Date of completion of search	Examiner
The Hague	26 April 91	MOERS R.J.

CATEGORY OF CITED DOCUMENTS

X: particularly relevant if taken alone
Y: particularly relevant if combined with another document of the same catagory
A: technological background
O: non-written disclosure
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T: theory or principle underlying the invention

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